

4267 FIRST AID KIT- 4267 first aid kit

Honeywell Safety Products USA, INC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

4267 First Aid Kit (Neomycin, EW, ammonia inh, alcohol wipes, Burn Sray, Antiseptic Spray, Hand Sanitizer, aypanal- FAK3SHLF-CLSB)

Eyesaline

Active ingredient

Sterile Water 99%

Eyesaline

Purpose

Eyewash

Eyesaline

Uses

- for flushing the eye to remove loose foreign material, air pollutants or chlorinated water

Eyesaline

Warnings

For external use only-

Obtain immediate medical treatment for all open wounds in or near eyes.

To avoid contamination, do not touch tip of container to any surface.

Do not reuse. Once opened, discard.

Do not use

- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes, get medical help right away.

Stop use and ask a doctor if

- you experience eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Eyesaline

Directions

- remove contacts before using

- twist top to remove
- flush the affected area as needed
- control rate of flow by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

Eyesaline

Inactive ingredients

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyesaline

Questions

1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI 02917

Alcohol Wipe

Active ingredient

Isopropyl alcohol 70%

Alcohol Wipe

Purpose

First aid antiseptic

Alcohol Wipe

Uses

- first aid to help prevent infection in minor cuts, scrapes, and burns

Alcohol Wipe

Warnings

For external use only

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burn

When using this product

- do not use longer than one week unless directed by a doctor

Stop use and consult a doctor

- if condition persists or gets worse

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away.

Alcohol Wipe***Directions***

- clean the affected area
- apply wipe to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard wipe after single use

Alcohol Wipe***Other information***

store at room temperature 15 ° to 25 ° C (59 ° to 77 °F)

Alcohol Wipe***Inactive ingredient***

water

Alcohol Wipe***Questions***

1-800-430-5490

Aypanal***Active ingredient***

Acetaminophen 325 mg

Aypanal***Purpose***

Pain reliever/ fever reducer

Aypanaly***Uses***

- temporarily relieves minor aches and pains due to the common cold and headache - temporarily reduces fever

Keep out of reach of children.

Keep out of reach of children.

Aypanal***Warnings***

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen

- adult has 3 or more alcoholic drinks every day while using this product:

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- If a skin rash occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription).
- If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease

Ask a doctor or pharmacist before use if

- you are taking the blood thinning drug warfarin

Stop using and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Overdose warning

- In case of accidental overdose, get medical help or contact a Poison Control Center right away.
- Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Aypanal

Directions

do not take more than directed (see overdose warning)

▯adults and children 12 years of age or older

- take two tablets every 4-6 hours while symptoms last
- do not take more than 12 tablets in 24 hours

children 6 to under 12 years of age

- take 1 tablet every 4-6 hours while symptoms last
- do not take more than 5 tablets in 24 hours

children under 6 years consult a doctor

Aypanal

Other information

- store at room temperature 15⁰ to 30⁰ C (59⁰ - 86⁰ F)
- TAMPER EVIDENT PACKETS- DO NOT USE IF OPEN OR TORN

Aypanal***Inactive ingredients***

corn starch, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid

Aypanal***Questions***

1-800-430-5490

Neomycin***Active ingredient***

Neomycin sulfate (5 mg equivalent to 3.5 mg Neomycin base)

Neomycin***Purpose***

First aid antibiotic

Neomycin***Uses***

- first aid to help prevent infection in - minor cuts - scrapes - burns

Do not use

- in the eyes
- over large areas of the body

Neomycin***Warnings*****For external use only****Do not use**

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- a rash or other allergic reaction develops
- you need to use longer than 1 week

Stop use and ask a doctor if

- the condition persists or gets worse
- a rash or other allergic reaction develops
- you need to use longer than 1 week

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away

Neomycin***Direction***

- clean the affected area
- apply a small amount of the product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage

Neomycin***Other information***

store at 15⁰ to 25⁰ C (59⁰ to 77⁰ F)

Neomycin***Inactive ingredient***

petrolatum

Neomycin***Questions?***

1-800-430-5490

Antiseptic Spray***Active ingredient***

Benzalkonium chloride 0.13%

Antiseptic Spray***Purpose***

First aid antiseptic

Antiseptic Spray***Uses***

- first aid to help prevent infection in minor cuts, scrapes and burns

Antiseptic Spray***Warnings*****For external use only****Do not use**

- in or near the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if

- the condition persists or gets worse

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away

Antiseptic Spray

Directions

- clean the affected area
- spray a small amount of this product on the area 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

Antiseptic Spray

Other information

- shake well
- store at room temperature 15 °-30 ° C (59 ° -86 ° F)

Antiseptic Spray

Inactive ingredients

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, trolamine, water

Antiseptic Spray

Questions

1-800-430-5490

Burn Spray

Active ingredient

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

Burn Spray

Purpose

Benzethonium chloride 0.2% w/w

Benzocaine 10% w/w

Menthol 0.33% w/w

Burn Spray

Uses

for the temporary relief of pain and itching and helps protect against infection in:

- minor cuts and scrapes
- burns
- sunburn
- insect bites
- minor skin irritations

Burn Spray

Warnings

For external use only

Flammable

- keep away from fire or flame
- contents under pressure
- do not puncture or incinerate container
- do not expose to temperatures above 120 °F

Do not use

- in or near the eyes or other mucous membranes
- in case of serious burns
- in case of deep or puncture wounds
- for prolonged period of time
- on large portion of the body

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- condition clears up and recurs within a few days
- redness, swelling, or irritation occurs

Keep out of the reach of children

- If swallowed, get medical help or contact a Poison Control Center right away.

Burn Spray

Directions

- clean the affected area
- shake can well before using
- hold 4 - 6 inches from surface and spray area until wet
- may be covered with a sterile bandage, if bandaged let dry first
- for adult institutional use only
- not intended for use on children

Burn Spray

Other information

- avoid inhaling
- use only as directed
- intentional misuse by deliberately concentrating or inhaling the contents may be harmful or fatal

Burn Spray***Inactive ingredients***

dipropylene glycol, isobutane, n-butane, propane

Hand Sanitizer***Active ingredient***

Ethyl alcohol 62%

Hand Santizer***Purpose***

Antiseptic handwash

Hand Sanitizer***Uses***

- for hand washing to decrease bacteria on skin
- recommended for repeated use

Hand Sanitizer***Warnings***

For external use only

Flammable, keep away from fire or flame

When using this product

- do not use in the eyes
- discontinue use if irritation and redness develops. If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Hand Sanitizer***Directions***

- wet hands thoroughly with product and allow to dry without wiping

Hand Sanitizer***Other information***

store at 15 ° to 25 ° C (59 ° to 77 ° F)

Hand Sanitizer***Inactive ingredients***

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, dl-alpha tocopheryl acetate, fragrance, PEG-60 almond glycerides, propylene glycol, purified water, triisopropanolamine

Hand Sanitizer

Questions or Comments?

1-800-275-3433 info@waterjel.com www.waterjel.com

Ammonia

Active ingredient

Ammonia 15%

Ammonia

Purpose

Respiratory stimulant

Ammonia

Uses

- to prevent or treat fainting

Ammonia

Warnings

For external use only

Do not use

- if you have breathing problems such as asthma or emphysema

Stop use and ask a doctor if

- condition persists

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away.

Ammonia

Directions

- hold inhalant away from face and crush ampoule between thumb and forefinger at position indicated on sleeve.
- hold near nostrils for inhalation of volatile vapor

Ammonia

Other information

- store at room temperature away from light

Ammonia

Inactive ingredients

alcohol USP, FD&C red #40, lavender oil, lemon oil fcc, nutmeg oil, purified water

Ammonia

Questions or Comments?

1-800-430-5490

Eyesaline

Principal Display Panel

Honeywell

TAMPER-EVIDENT CAP.
TAPA CON SELLO DE SEGURIDAD.
BOUCHON INDICATEUR D'INFRACTION.

LAVAOJOS
EYESALINE

EYESALINE
EYEWASH

LAVAGE
OCULAIRE
EYESALINE

Solución
Isotónico Estéril

Sterile
Isotonic Solution

La Solution
Isotonique Stérile

16 fl. oz. (473 mL)

NPN: 80057528

64809 11 45033 117

Drug Facts (for USA only)

Active ingredient Sterile water 99%	Purpose Eyewash
Uses for flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.	
Warnings For external use only - Obtain immediate medical treatment for all open wounds in or near the eyes. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not use • if solution changes color or becomes cloudy • if you have open wounds in or near the eyes, get medical help right away Stop use and consult a doctor if: • you experience eye pain • changes in vision • continued redness or irritation of the eye • condition worsens or persists Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • remove contacts before using • twist top to remove • flush the affected area as needed • control rate of flow by pressure on the bottle • if necessary, continue flushing with emergency eyewash or shower	
Inactive ingredients sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic	
Questions? Call 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917	

LABEL 832-00451/Rev. J REORDER / NÚMERO PEDIDO / RÉAPPROVISIONNEMENT 832-000454-0000

space for lot code and supplier part number

PEEL / PELAR / PELER

Datos de medicamento (Para EE.UU. solamente)

Ingrediente Activo Agua estéril 99%	Propósito Lavajojos
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Usos
para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aéreos, o agua de cloruro

Advertencias
Para el uso externo sólo - Obtenga tratamiento médico inmediato para todas las heridas abiertas en o cerca de los ojos. Para evitar la contaminación, no toque la punta del envase con ninguna superficie. No vuelva a usar. Vez abierto, descarte.
No se use • si la solución se enturbia o cambia de color
• si tiene heridas abiertas en o cerca del ojo, obtenga ayuda médica de inmediato
Deje de usar y consulte a un médico si:
• experimenta dolor de ojo • cambio de visión
• rojez continuo o irritación del ojo
• la condición empeora o persiste
Manténgase fuera del alcance de los niños.
En caso de ingestión accidental, obtenga atención médica o llame a un Centro de control de envenenamiento inmediatamente.

Instrucciones
• quítase los lentes de contacto antes de usar la solución
• fuerza la tapa para quitar
• enjuague el área afectada según se necesite
• controle el chorro haciendo presión en la botella
• si es necesario, sigue enjuagado con un lavajojos o ducha de emergencia

Ingredientes inactivos
cloruro de sodio, fosfato de sodio dibásico, fosfato de sodio monobásico

¿Preguntas? Llame al 1-800-430-5490
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Information

Usages
Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmosphériques ou de l'eau chlorée.

Advertissements
Pour usage externe seulement - Obtenir immédiatement des soins médicaux pour toutes les plaies ouvertes dans ou près des yeux. Pour éviter toute contamination, ne pas toucher la pointe du récipient à n'importe quelle surface. Ne pas réutiliser. Une fois ouvert, jeter-les.
Ne pas utiliser
• si la solution a changé de couleur ou si elle est trouble
• si vous avez des plaies ouvertes aux yeux ou à proximité, consultez immédiatement un médecin
Cesser d'utiliser la solution et consulter un médecin
• vous ressentez une douleur oculaire • si votre vision change
• rougeur ou irritation persistante des yeux
• condition empire ou persiste
Garder hors de la portée des enfants.
En cas d'ingestion, communiquer immédiatement avec un médecin ou avec un centre antipoison.

Mode d'emploi
• enlever les verres de contact avant l'utilisation • dévisser le bouchon pour l'enlever • rincer la zone touchée selon les besoins • ajuster le débit d'écoulement de la solution en augmentant ou en réduisant la pression exercée sur le contenant
• si nécessaire, continuer de rincer avec une solution de rinçage oculaire d'urgence ou une douche

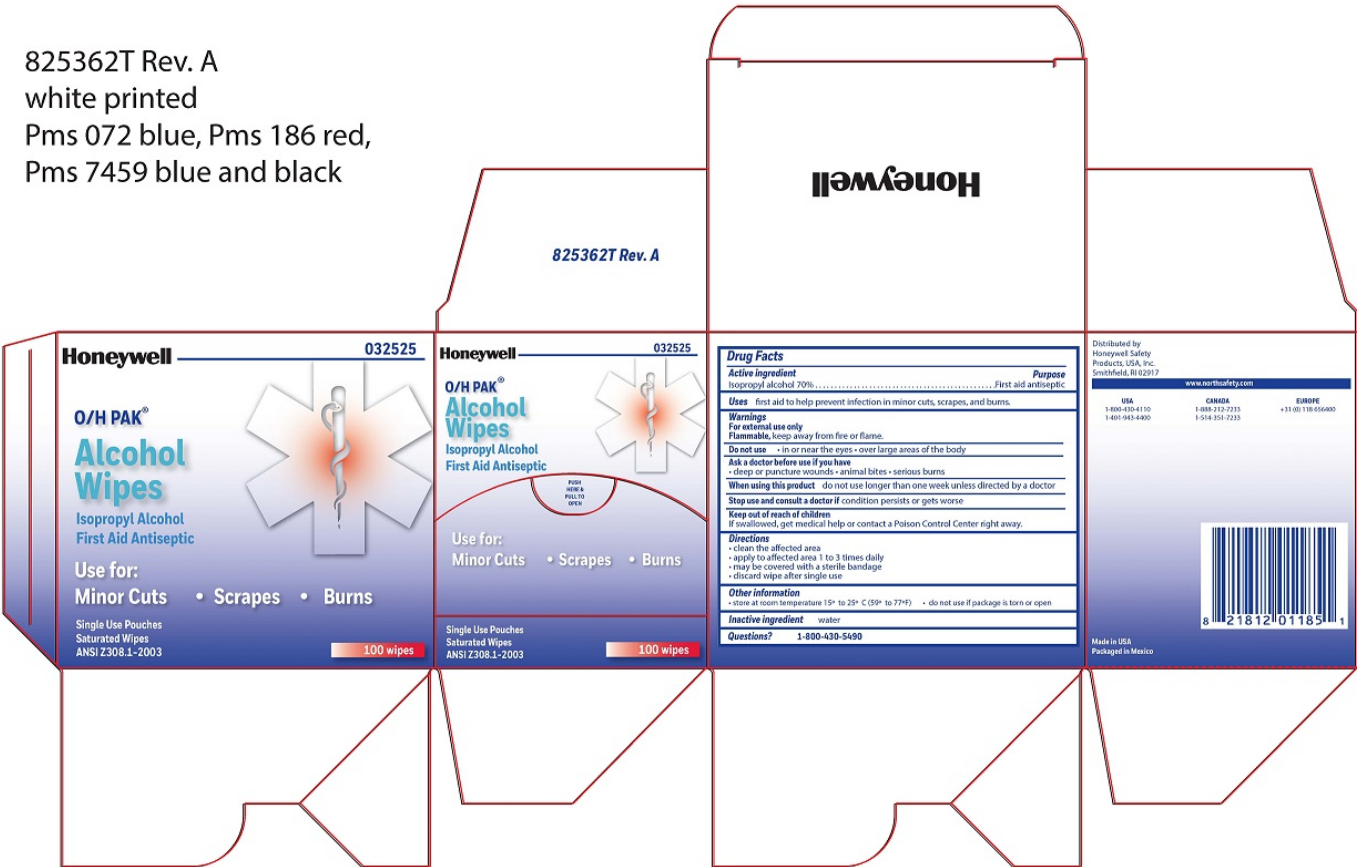
Ingédients eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium

Des questions? Faites le 1-800-430-5490
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

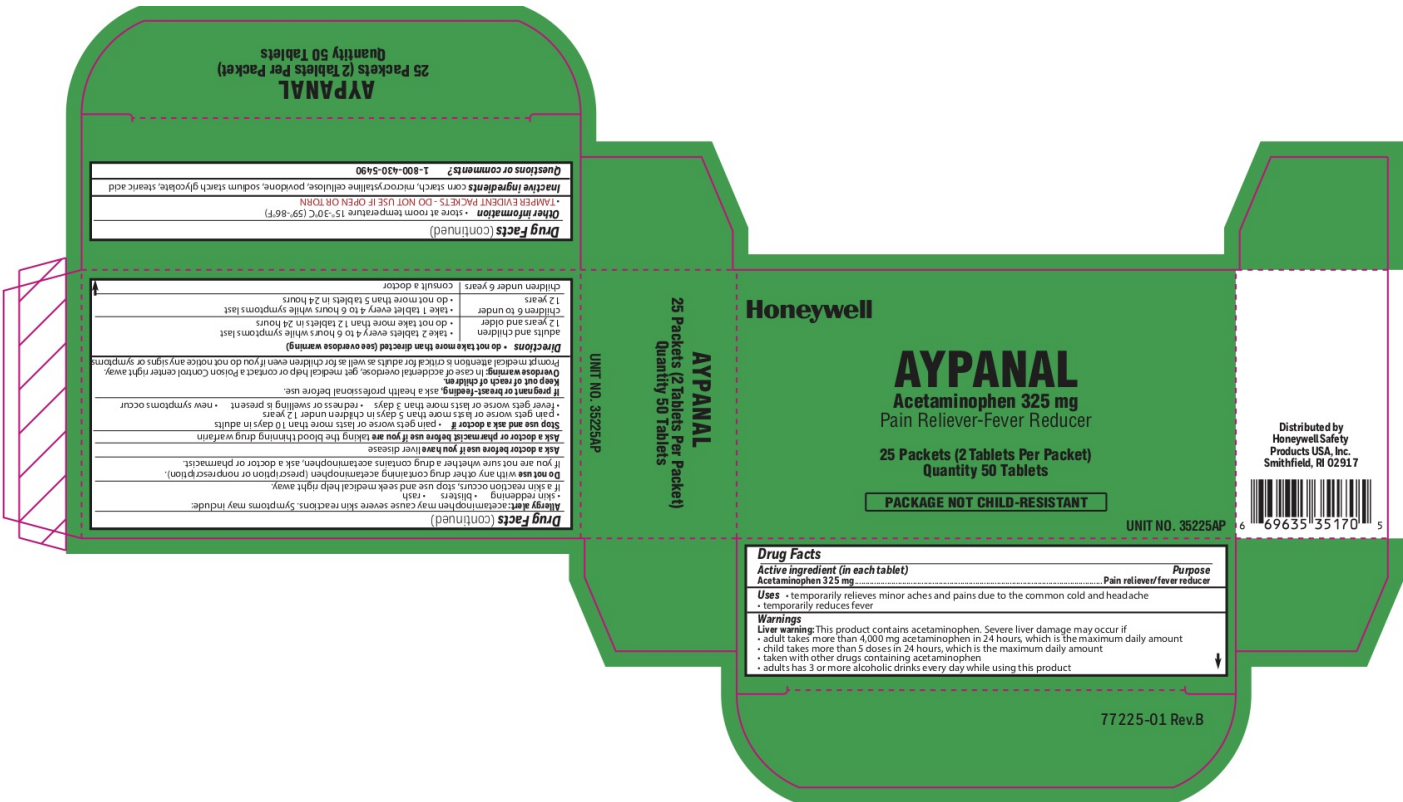
Alcohol Wipe

Principal Display Panel

825362T Rev. A
white printed
Pms 072 blue, Pms 186 red,
Pms 7459 blue and black

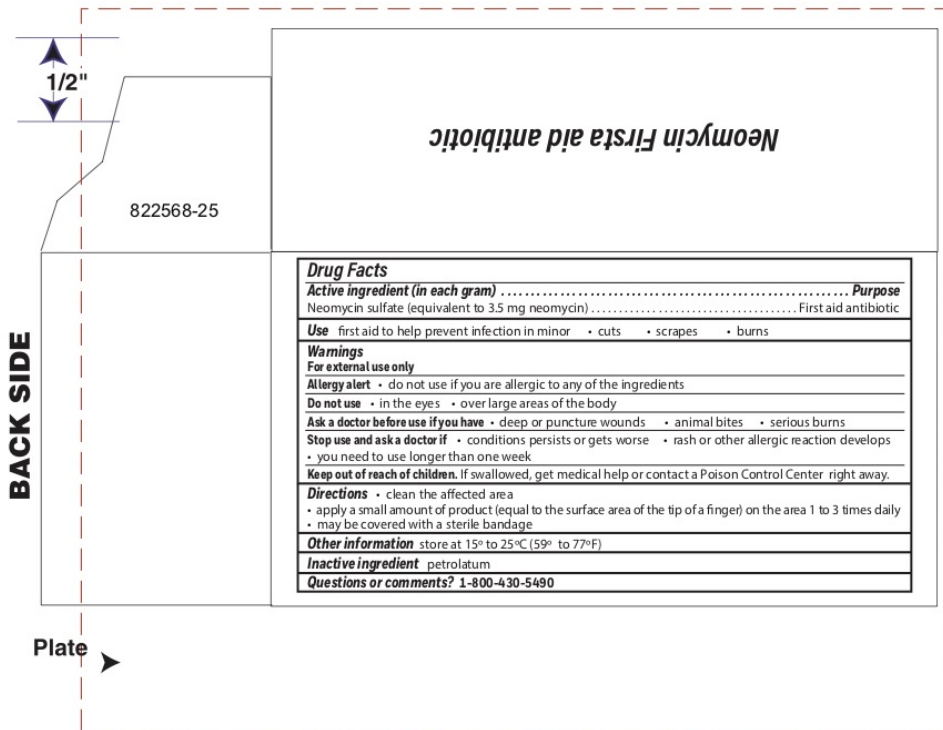
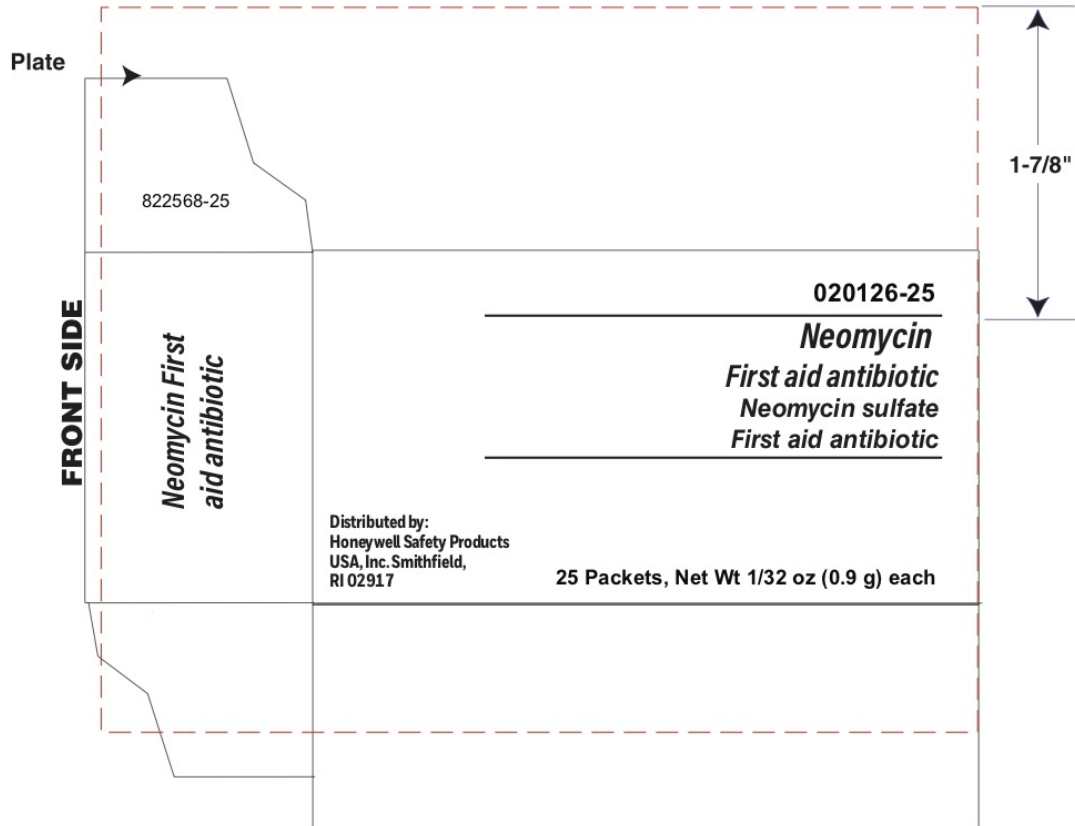


Aypanal
Principal Display Panel



Neomycin
Principal Display Panel

796041-25 Rev A Unit Carton Printing Plate for "C" size carton.



Antiseptic Spray
Principal Display Panel

Honeywell

032203



ANTISEPTIC
SPRAY

Benzalkonium
chloride

First Aid
Antiseptic

Net contents 2 fl oz (59 mL)

ANSI Z308.1-2003



8 21812 01498 2

Drug Facts

Active ingredient	Purpose
Benzalkonium chloride 0.13%	First aid antiseptic
Uses first aid to help prevent infection in minor cuts, scrapes and burns	
Warnings	
For external use only	
Do not use • in or near the eyes • over large areas of the body	
Ask a doctor before use if you have • deep or puncture wounds • animal bites • serious burns	
When using this product do not use longer than one week unless directed by a doctor	
Stop use and ask a doctor if condition persists or gets worse	
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.	
Directions • clean the affected area • spray a small amount of this product on the area 1 to 3 times daily • may be covered with a sterile bandage • if bandaged, let dry first	
Other information • shake well • store at room temperature, 15° to 30°C (59° to 86°F)	
Inactive ingredients diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, triethylamine, water	
Questions or comments? 1-800-430-5490	

Mfg. for: Honeywell Safety Products USA, Inc. Smithfield, RI 02917 002203 Rev. G

Burn Spray
Principal Display Panel

SHAKE WELL BEFORE USING

Honeywell

BURN SPRAY

Water soluble
Benzethonium chloride
Topical antiseptic
Benzocaine
Topical anesthetic
Menthol
Topical anesthetic

Provides antiseptic treatment
and helps relieve the pain of minor burns
and sunburn.

CAUTION: FLAMMABLE
Contents under pressure
Read warning on back panel.


NET WT. 3 OZ (85gm.)

47.0306

Cat. No. 201005

DRUG FACTS

Active ingredients	Purpose
Benzethonium chloride 0.2% w/w	Topical antiseptic
Benzocaine 10% w/w	Topical anesthetic
Menthol .33%	Topical anesthetic
Uses • for the temporary relief of pain and itching and helps to protect against infection in • minor cuts and scrapes • burns • sunburn • insect bites • minor skin irritations	
Warnings	
For external use only	
Flammable • keep away from fire or flame • contents under pressure • do not puncture or incinerate container • do not expose to temperatures above 120°F	
Do not use • in or near eyes or other mucous membranes • in case of serious burns • in case of deep or puncture wounds • for a prolonged period of time • on large portion of the body	
Stop use and ask a doctor if: • conditions worsens or symptoms persist for more than 7 days • condition clears up and recurs within a few days • redness, swelling or irritation occurs	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • clean the affected area • shake can well before using • hold 4-6 inches from surface and spray area until wet • may be covered with a sterile bandage. If bandaged, let dry first • for adult institutional use only • not intended for use on children	
Other information • avoid inhaling • use only as directed • intentional misuse by deliberately concentrating and inhaling the contents may be harmful or fatal	
Inactive ingredients dipropylene glycol, isobutane, n-butane, propane	
Questions or comments? 1-800-430-5490	



6 69635 20032 4

Distributed by
Honeywell Safety
Products USA, Inc.
Smithfield, RI 02917

Honeywell



INSTANT

Hand Sanitizer

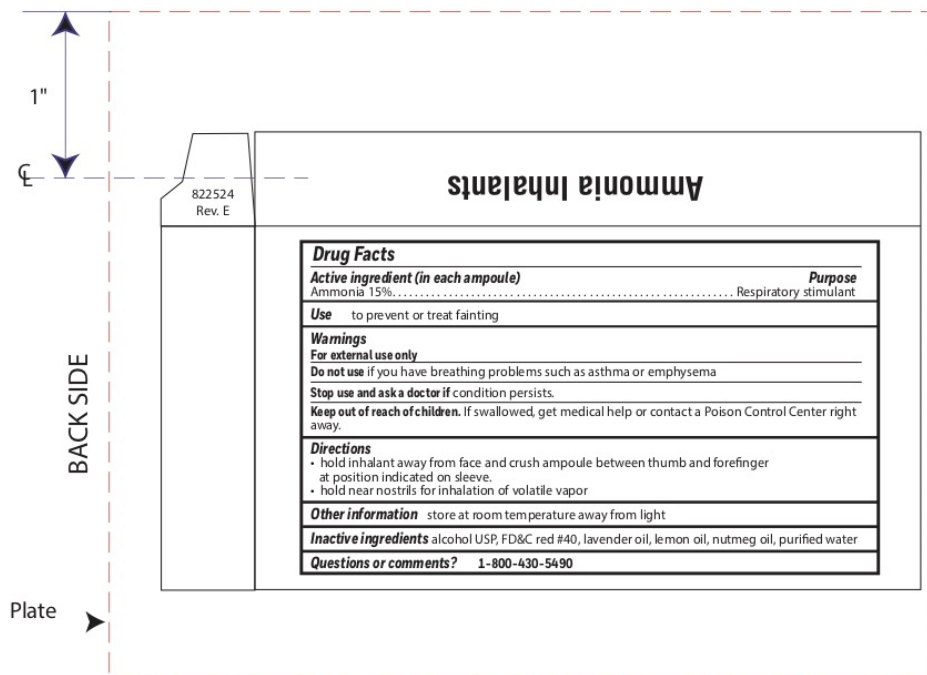
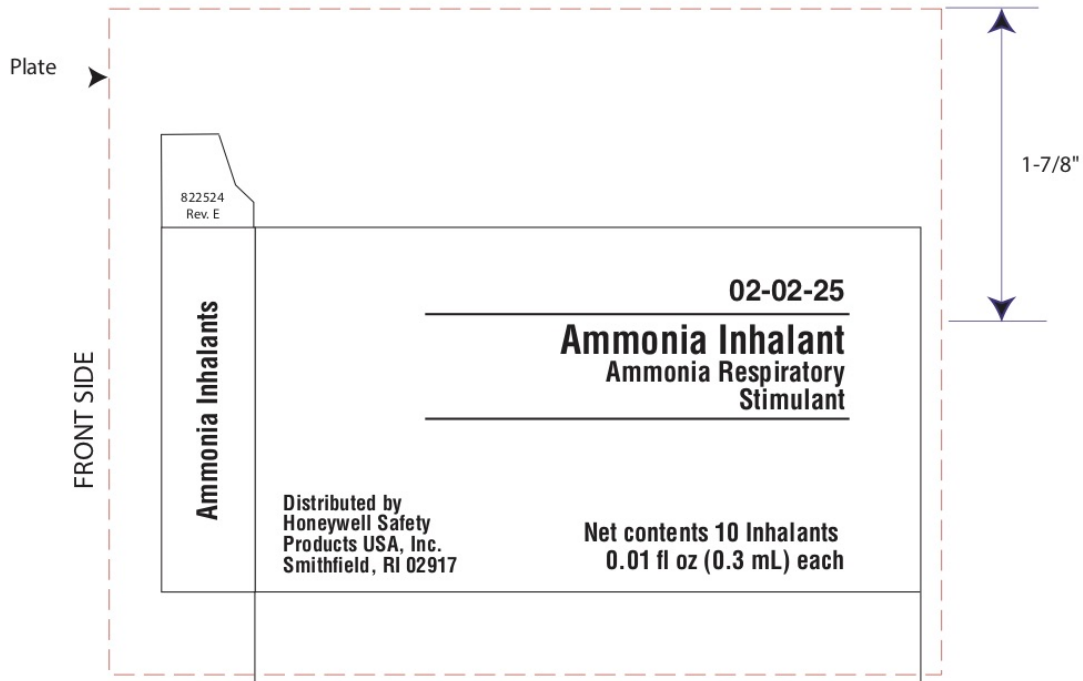
**Antiseptic Gel
With Vitamin E & Aloe**

***Kills 99.9% of Germs
Without Water***

240mL - (8 fl oz)

Ammonia
Principal Display Panel

796006 Rev. E Unit Carton Printing Plate for "A" size carton.



FAK3SHLF-CLSB

777028B Rev. A
white printed four color process
blue (pms 072C) and red (pms 186C)



4267 Kit Contents FAK3SHLF-CLSB

- 1 1X3 PLASTIC 100/BOX
- 1 FINGERTIP "T" WOVEN 40/BOX
- 1 SWIFT KNUCKLE 40/BX
- 1 1 X 3 WOVEN 100/BOX
- 3 NEOMYCIN ANTIBIOTIC 10 PER
- 1 AMMONIA INHALANTS 10 PER
- 2 EYE DRESS PKT W/4 ADH STRIPS
- 1 TOURNIQUET, 1 PER
- 1 WIRE SPLINT 1 PER
- 1 ADH BAND, EXTRA LARGE, 6 PER
- 1 ALCOHOL PREP PADS 10P
- 1 O/H PUMP ANTISEPTIC 2 OZ ID F
- 1 O/H PUMP BURN RELIEF 2 OZ ID G
- 1 FIRST AID GUIDE ASHI
- 2 TAPE ADHESIVE 1"X 5 YD PLSTC
- 10 HAND SANITIZER 0.9G WJ BULK

4 GAUZE CLEAN-WRAP BDGE N/S 2"
 4 GAUZE CLEAN-WRAP BDGE N/S 4"
 4 BLOODSTOPPER
 1 NON-ADHERENT PADS 2"X3" 10'S
 1 GZE PADS STERILE 2"X 2" 10'S
 1 GZE PADS STERILE 3"X 3" 25'S
 1 ELASTIC BANDAGE 3" X 4.5YD
 1 CPR FILTERSHIELD 77-100
 1 COTTON TIPS 100 PER VIAL
 1 AYPANAL NON-ASP IND 2/ENV 100
 1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
 1 SCISSOR BDGE 4" RED PLS HDL
 1 KIT TWEEZER 3 1/2" SLANTED
 1 180 EMPTY BLANK NO LOGO
 1 POCKET INSERT RED #180 KIT 4R
 1 TONGUE BLADES SR WRAPPED 6'S
 1 LBL STOCK 6-3/8"X4"
 1 LBL STOCK 4"X2-7/8"
 1 LBL STOCK 3"x1-7/8"
 4 PR LRG NITRILE GLVES ZIP BAG
 2 WATER-JEL BURN DRESSING 4 X 4
 1 LBL CONTENTS ANSI 2015 CL B
 1 LBL CAB CVR ANSI 2015 CL B
 2 TRI BNDG NON WOVEN 40"X40"X56"
 2 COLD PACK UNIT 4"X6" BULK
 1 RED BIO BAGS 2/BX

4267 FIRST AID KIT

4267 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4267
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4267-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	10 POUCH	4 mL
Part 3	50 PACKET	100
Part 4	1 BOTTLE, SPRAY	59 mL
Part 5	1 BOTTLE, SPRAY	59 mL
Part 6	30 PACKET	27 g
Part 7	10 PACKAGE	9 mL
Part 8	10 AMPULE	3 mL

Part 1 of 8

EYESALINE EMERGENCY EYEWASH

purified water liquid

Product Information

Item Code (Source)	NDC:0498-0100
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	98.6 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0100-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	12/18/2018	

Part 2 of 8

ALCOHOL WIPE

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:0498-0143
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2018	

Part 3 of 8

AYPANAL NON-ASPIRIN

acetaminophen tablet

Product Information

Item Code (Source)	NDC:0498-2001
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	white	Score	2 pieces
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	circle;U
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/10/2012	

Part 4 of 8
BURN RELIEF
lidocaine hydrochloride spray

Product Information	
Item Code (Source)	NDC:0498-0221
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	24.64 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	

TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VF565UC2G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0221-59	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/18/2018	

Part 5 of 8

ANTISEPTIC

benzalkonium chloride spray

Product Information

Item Code (Source)	NDC:0498-0402
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0402-59	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/18/2018	

Part 6 of 8

NEOMYCIN

antibiotic ointment

Product Information

Item Code (Source)	NDC:0498-0730
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0730-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	03/31/2010	

Part 7 of 8

INSTANT HAND SANITIZER

alcohol liquid

Product Information

Item Code (Source)	NDC:59898-420
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
WATER (UNII: 059QF0KO0R)	
TRIISOPROPANOLAMINE (UNII: W9EN9DLM98)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-420-36	0.9 mL in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/15/2010	

Part 8 of 8

AMMONIA INHALENT

ammonia inhalent inhalant

Product Information	
Item Code (Source)	NDC:0498-3334
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AMMONIA (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X)	AMMONIA	0.045 g in 0.3 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-3334-00	0.3 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

Labeler - Honeywell Safety Products USA, INC (079287321)

Establishment			
Name	Address	ID/FEI	Business Operations
James Alexander		040756421	manufacture(0498-3334)

Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4267)

Establishment			
Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	manufacture(0498-2001)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0730, 0498-0402, 0498-0221, 59898-420)

Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc.		167518617	manufacture(0498-0100)

Establishment			
Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0143)